Complete Summary

GUIDELINE TITLE

Relief of pain and anxiety in pediatric patients in emergency medical systems.

BIBLIOGRAPHIC SOURCE(S)

Zempsky WT, Cravero JP. Relief of pain and anxiety in pediatric patients in emergency medical systems. Pediatrics 2004 Nov; 114(5): 1348-56. [143 references] <u>PubMed</u>

GUIDELINE STATUS

This is the current release of the guideline.

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** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

On April 7, 2005, after concluding that the overall risk versus benefit profile is unfavorable, the FDA requested that Pfizer, Inc voluntarily withdraw Bextra (valdecoxib) from the market. The FDA also asked manufacturers of all marketed prescription nonsteroidal anti-inflammatory drugs (NSAIDs), including Celebrex (celecoxib), a COX-2 selective NSAID, to revise the labeling (package insert) for their products to include a boxed warning and a Medication Guide. Finally, FDA asked manufacturers of non-prescription (over the counter [OTC]) NSAIDs to revise their labeling to include more specific information about the potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drug. See the <u>FDA Web site</u> for more information.

Subsequently, on June 15, 2005, the FDA requested that sponsors of all non-steroidal anti-inflammatory drugs (NSAID) make labeling changes to their products. FDA recommended proposed labeling for both the prescription and over-the-counter (OTC) NSAIDs and a medication guide for the entire class of prescription products. All sponsors of marketed prescription NSAIDs, including Celebrex (celecoxib), a COX-2 selective NSAID, have been asked to revise the

labeling (package insert) for their products to include a boxed warning, highlighting the potential for increased risk of cardiovascular (CV) events and the well described, serious, potential life-threatening gastrointestinal (GI) bleeding associated with their use. FDA regulation 21CFR 208 requires a Medication Guide to be provided with each prescription that is dispensed for products that FDA determines pose a serious and significant public health concern. See the <u>FDA Web</u> site for more information.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

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SCOPE

DISEASE/CONDITION(S)

Pain and/or stress that is caused by a disease process, a result of acute injury, or a product of a diagnostic or therapeutic procedure

GUIDELINE CATEGORY

Evaluation Management Treatment

CLINICAL SPECIALTY

Emergency Medicine Family Practice Pediatrics

INTENDED USERS

Advanced Practice Nurses Emergency Medical Technicians/Paramedics Nurses Physician Assistants Physicians

GUI DELI NE OBJECTI VE(S)

To provide information to optimize the comfort of children whether they are cared for in the emergency setting or other environments

TARGET POPULATION

Children who enter into the emergency medical system

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation/Management

- 1. Non-pharmacological or stress management and emotional support via friendly, calming environment, distraction techniques, child life specialists, and family presence
- 2. Pain assessment
 - Self-report scales (Wong-Baker Faces Scale; 10-cm Visual Analog Scale)
 - Behavioral scales in combination with an evaluation of patient's history and physical findings
- 3. Triage patients

Treatment

Minor Procedures

- 1. Acetaminophen
- 2. Ibuprofen
- 3. Oral opiates
- 4. Topical anesthetics
 - Eutectic mixture of local anesthetics (EMLA)
 - Liposomal 4% lidocaine cream (LMX₄)
 - Lidocaine iontophoresis
 - Vapocoolant sprays
 - Lidocaine, epinephrine, tetracaine (LET)
- 5. Tissue adhesives
 - Octyl cyanoacrylate
 - Steri-Strips
- 6. Lidocaine (injected)

Neonatal Pain Management in the Emergency Department (ED)

- 1. EMLA
- 2. Sucrose
- 3. Pacifier alone or with sucrose
- 4. Skin-to-skin contact of mother to infant
- 5. Local and topical anesthesia for lumbar puncture
- 6. Elimination of heel sticks and intramuscular injection

Administration of Pain Medications

- 1. Adjunctive pain medications (e.g., nonsteroidal anti-inflammatory drugs [NSAIDs])
- 2. Consideration of alternative routes including oral, intranasal, transdermal, and inhaled
- 3. Nitrous oxide
- 4. Appropriate pain medication on discharge

Sedation

- 1. Sedative hypnotic medication
- 2. Development of policies for close monitoring of patients receiving sedation

MAJOR OUTCOMES CONSIDERED

- Efficacy of intervention strategies in minimizing pain and anxiety and promoting comfort
- Safety of medication used to manage pain and anxiety

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Informal Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Triage Oral Analgesic Administration Guidelines

Purpose

To provide analgesic therapy to patients presenting to triage with a complaint of pain

Procedure

- 1. Pain assessment
- 2. Immediate triage to department for all those with severe pain as assessed by triage nurse and consideration of pain score
- 3. For those not requiring immediate evaluation with pain score >3 (0-10 scale) or chief complaint consistent with pain, consider administration of oral analgesic
- 4. Assess recent analgesic use

Contraindications

- 1. Allergy to analgesic (consider alternative)
- 2. Nothing by mouth (NPO) status (if patient may require procedural sedation or general anesthesia, consult with a physician before analgesic administration)

Medications

- 1. Ibuprofen (avoid if the patient has an aspirin allergy, anticipated surgery, bleeding disorder, hemorrhage, or renal disease)
- 2. Acetaminophen (avoid if the patient has hepatic disease or dysfunction)
- 3. Acetaminophen with codeine or other oral opiate

Guidelines for the Use of Eutectic Mixture of Local Anesthetics/Liposomal 4% Lidocaine Cream (EMLA/LMX₄) in the Emergency Department (ED)

EMLA/LMX₄ use should be considered in any patient who has a high likelihood of undergoing a nonemergent invasive procedure on intact skin in the ED. These include:

- Intravenous line placement or venipuncture
- Lumbar puncture
- Abscess drainage
- Joint aspiration

Discussion with parents should bring up these issues:

- EMLA/LMX₄ does not provide complete pain relief
- Some patients may require a procedure before EMLA/LMX₄ reaches its full effectiveness (see below)

Contraindications

- Emergent need for intravenous access
- Allergy to amide anesthetics
- Nonintact skin
- Recent sulfonamide antibiotic use (trimethoprim-sulfamethoxazole, erythromycin-sulfisoxazole) (EMLA only)
- Congenital or idiopathic methemoglobinemia (EMLA only)

The EMLA dose should be lower for patients <12 months old or weighing <10 kg

Placement of EMLA/LMX₄

- Intravenous line placement
 - EMLA/LMX₄ should be placed in at least 2 sites over veins amenable to placement of an intravenous line as judged by the triage nurse.
 - EMLA reaches full effectiveness in 1 h; LMX₄ reaches full effectiveness in 30 min.
 - Care should be taken to avoid mucous membrane contact or ingestion.
- Lumbar puncture

• Placement of EMLA/LMX₄ for lumbar puncture should be considered at triage; accurate placement requires consultation with the attending physician.

<u>Triage Guidelines for use of Lidocaine, Epinephrine, Tetracaine (LET) (a Topical Anesthetic for Open Wounds</u>

Eligibility

• Simple lacerations of the head, neck, extremities, or trunk <5 cm in length

Contraindications

- Allergy to amide anesthetics
- Gross contamination of wound
- Involvement of mucous membranes, digits, genitalia, ear, or nose

Procedure

- LET should be placed according to standard ED procedure; time of placement should be documented on triage sheet.
- Maximum wound length: 5 cm; maximum dose: 3 mL
 - (1) Place 3 mL of LET mixed with cellulose on open wound and cover with occlusive dressing or (2) place cotton ball soaked with LET solution into wound

Guidelines for the Use of Sucrose in the ED

Indications

• Use as an adjunct for limiting the pain associated with procedures such as heel sticks, venipuncture, intravenous line insertion, arterial puncture, insertion of a Foley catheter, and lumbar puncture in neonates and infants younger than 6 months.

Procedure

- 1. Administer 2 mL of 25% sucrose solution by syringe into the infant's mouth (1 mL in each cheek) or allow infant to suck solution from a nipple (pacifier) no more than 2 min before the start of the painful procedure.
- 2. Sucrose may be given for >1 procedure within a relatively short period of time but should not be administered more than twice in 1 hour.
- 3. Sucrose seems to be more effective when given in combination with a pacifier; nonnutritive suck also contributes to calming the infant and decreasing pain-elicited distress.

Contraindications

Avoid use if patient is under NPO restrictions.

Summary of Key Points

- 1. Training and education in pediatric pain assessment and management should be provided to all participants in emergency medical systems for children.
- 2. Simple methods for creating favorable environmental conditions for pediatric patients in the emergency medical services (EMS) setting should be advocated by caregivers.
- 3. Incorporation of child life specialists and others trained in nonpharmacologic stress reduction should be encouraged.
- 4. Family presence should be offered as an option during painful procedures.
- 5. Pain assessment for children should begin at admission to EMS and continue until discharge from the ED. On discharge, patients should receive detailed instruction regarding analyses administration.
- 6. Painless administration of analgesics and anesthetics should be practiced when possible.
- 7. Neonates and young infants should receive appropriate pain relief.
- 8. Administration of pain medication has not been shown to hinder the evaluation of a possible surgical patient in the ED, and pain medication should not be withheld on this account.
- 9. Sedation should be provided for patients undergoing painful or stressful procedures in the ED. A structured protocol for pediatric sedation, based on American Academy of Pediatrics (AAP), American Society of Anesthesiologists (ASA), American College of Emergency Physicians, and Emergency Medical Services for Children recommendations, should be followed for all children who receive sedative medications in EMS.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting each recommendation is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Adequate pain assessment
- Control of pain and stress and optimization of comfort for children who enter into the emergency medical system

POTENTIAL HARMS

- Approximately 5% of children find the sensation caused by iontophoretic drug delivery to be unpleasant.
- Nonsteroidal anti-inflammatory drugs have the following known side effects: antiplatelet activity and gastrointestinal and renal toxicity.

• Combinations of medications, particularly the addition of opiates to sedative medications, may increase the risk of respiratory depression and should only be used by individuals trained in airway management and resuscitation.

CONTRAINDICATIONS

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Analgesic Therapy

- Allergy to analgesic (consider alternative)
- Nothing by mouth (NPO) status (if patient may require procedural sedation or general anesthesia, consult with a physician before analgesic administration)

Eutectic Mixture of Local Anesthetics/Liposomal 4% Lidocaine Cream (EMLA/LMX₄)

- Emergent need for intravenous access
- Allergy to amide anesthetics
- Nonintact skin
- Recent sulfonamide antibiotic use (trimethoprim-sulfamethoxazole, erythromycin-sulfisoxazole) (EMLA only)
- Congenital or idiopathic methemoglobinemia (EMLA only)

Lidocaine, Epinephrine, Tetracaine (LET)

- Allergy to amide anesthetics
- Gross contamination of wound
- Involvement of mucous membranes, digits, genitalia, ear, or nose

Nitrous Oxide

• Nitrous oxide should be avoided in patients with pneumothorax, bowel obstruction, intracranial injury, and cardiovascular compromise.

Sucrose

• Avoid use if patient is under NPO restrictions

QUALIFYING STATEMENTS

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The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Staying Healthy

IOM DOMAIN

Effectiveness Patient-centeredness Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Nov

GUIDELINE DEVELOPER(S)

American Academy of Pediatrics - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Pediatrics

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: Available from the <u>American Academy of Pediatrics (AAP) Policy Web site</u>.

Print copies: Available from American Academy of Pediatrics, 141 Northwest Point Blvd., P.O. Box 927, Elk Grove Village, IL 60009-0927.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on January 11, 2005. The information was verified by the guideline developer on February 10, 2005. This summary was updated on May 3, 2005 following the withdrawal of Bextra (valdecoxib) from the market and the release of heightened warnings for Celebrex (celecoxib) and other nonselective nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI on June 16, 2005, following the U.S. Food and Drug Administration advisory on COX-2 selective and non-selective non-steroidal anti-inflammatory drugs (NSAIDs).

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